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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,567	05/12/2005	Jean-Francois Biegun	CAC.P0046	6534
7590 Edward G Greive Renner Kenner Greive Bobak Taylor & Weber Fourth Floor First National Tower Akron, OH 44308-1456			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 10/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/534,567

Applicant(s)

BIEGUN ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12, 13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This action is in response to applicant's amendment received on 07/12/2007.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/12/2007 has been entered.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12, 13, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masini (U.S. Patent 5,897,559) in view of Merrill (U.S. Publication 2003/0119935).

Regarding claim 21, Masini discloses various embodiments, such as Figure 4, of a device comprising a part made of plastic, such as polyethylene, capable of being in contact with bone to be removed and capable of removing the bone when the device is being used. Masini discloses a device comprising a body that may be made from a polyethylene (column 2 lines 16-21) placed upon the surface of a bone. The body is

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configured to receive an insert (424), wherein the insert that may be made from metal, plastic, or any other suitable material, such as memory shape materials. Regarding claim 15, Masini discloses a device wherein the part made of plastic comprises at least one insert of a material harder than bone, such as metal, wherein the insert is at least partially embedded in the plastic material. Regarding claim 16 Masini discloses a device wherein the at least one insert is fully embedded in the plastic material. The insert is placed within the plastic body and is completely embedded within the walls of the plastic body. Regarding claims 17 and 18, Masini discloses a device wherein the at least one insert is metal. Masini fails to disclose a device wherein the plastic deteriorates when placed in an autoclave at a temperature of at least 137 degrees Celsius. Merrill teaches a device comprised of a radiation treated ultra high molecular weight polyethylene, which can be treated with gamma radiation (page 1 paragraph 10), that has a melting point of 137 degrees Celsius (page 4 paragraph 051) in order to improve the wear resistance of the device (page 1 paragraph 09). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Masini wherein the body is made from a radiation treated ultra high molecular weight polyethylene in view of Merrill in order to improve wear resistance of the device.

Further regarding claim 21, the combination of Masini and Merrill disclose a device capable of removing bone when the device is used and that is capable of deteriorating and no longer being used when put into an autoclave set at least to 137 degrees Celsius. Regarding claim 20, the combination of Masini and Merrill disclose a device inherently capable of being made by a method comprising the steps of providing

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a body having the shape of an ancillary and comprising a part made of plastic material which is to come into contact with the bone to be removed, wherein the part is capable of removing the bone when the device is used to remove the bone, and exposing the plastic material to gamma or beta radiation so the plastic material is hard enough to remove bone when the device is used and when the device is put into an autoclave set to at least 137 degrees Celsius the device deteriorates and is not longer capable of being used. Regarding claim 12, the combination of Masini and Merrill disclose a device inherently capable of being made by a method as discussed above further comprising the step of embedding at least one insert of a material harder than bone in the plastic material. Regarding claim 13, the combination of Masini and Merrill discloses a device inherently capable of being made by a method as discussed above wherein the at least one insert is fully embedded in the plastic material.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 12, 13, and 15-21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW



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SUPERVISOR, PATENT EXAMINER